CASE NO. 09-CI-002273

JEFFERSON CIRCUIT COURT
DIVISION ELEVEN (11)
JUDGE FREDERIC COWAN

On behalf of themselves and all others similarly situated within the Commonwealth of Kentucky,

CARLA YORK and HAROLD RICHARDSON, Co-Executors of THE ESTATE OF EARL LONEY

and

JUDY A. WHITAKER, as the Executrix of THE ESTATE OF ANNA FIGHT

and

IRMA WRIGHT

and

VETA COON

and

LORENA ARD

and

MARY BOND

and

REGENE FLEMING

PLAINTIFFS

v.

ACTAVIS TOTOWA, LLC

Serve: Kentucky Secretary of State
Summonses Branch
700 Capital Avenue, Suite 86
Frankfort, KY 40601

Serve: Sigurdur Oli Olafsson
Actavis Totowa, LLC
60 Columbia Rd.
Building B

Morristown, NJ 07960

and

MYLAN PHARMACEUTICALS, INC.

Serve: Kentucky Secretary of State
Summonses Branch
700 Capital Avenue, Suite 86
Frankfort, KY 40601

Serve: Harry A. Korman
Mylan Pharmaceuticals, Inc.
781 Chestnut Ridge Rd.
Morgantown, WV 26505

and

UDL LABORATORIES, INC.

Serve: Kentucky Secretary of State
Summonses Branch
700 Capital Avenue, Suite 86
Frankfort, KY 40601

Serve: Harry Korman
UDL Laboratories, Inc.
781 Chestnut Ridge Rd.
Morgantown, WV 26505

DEFENDANTS

AMENDED COMPLAINT

Plaintiffs, on behalf of themselves and all others similarly situated within the Commonwealth of Kentucky, state the following as their Amended Complaint against the Defendants:

1. Plaintiffs bring this claim for injury and wrongful death against the Defendants for designing, manufacturing, producing, supplying, inadequately inspecting, testing, selling and distributing dangerous, defective, misbranded, and adulterated Digitek® (digoxin tablets, USP) (hereinafter, "Digitek") containing an amount of the drug's active ingredient, digoxin, exceeding the dose set forth on the label and in some cases exceeding the dose approved for medical

treatment in humans. By reason of the wrongful conduct of the Defendants, and the dangers posed by the potential for overdoses of the drug, a massive, national recall of Digitek® tablets has been initiated in the United States. Additionally, Plaintiffs, on behalf of themselves and all others similarly situated within the Commonwealth of Kentucky, bring claims for reimbursement for the cost of all recalled and/or defective pills sold by the Defendants.

2. This Court has subject matter jurisdiction because the Digitek® tablets were distributed within the Commonwealth of Kentucky and the Plaintiffs were injured and/or treated within the Commonwealth of Kentucky.

3. The Defendants are subject to the personal jurisdiction of this Court pursuant to KRS 454.210 because their conduct caused injury and/or death to the Plaintiffs in this state.

4. Earl Loney was at all times relevant herein a Kentucky citizen who ingested Digitek® pursuant to a physician's prescription and suffered serious personal injuries, as a result of his ingestion of Digitek®, which injuries ultimately led to his death on January 18, 2008.

5. Anna Fight was at all times relevant herein a Kentucky citizen who ingested Digitek® pursuant to a physician's prescription and suffered serious personal injuries, including stroke, as a result of her ingestion of Digitek®, which injuries ultimately led to her death on May 13, 2007.

6. Veta Coon was at all times relevant herein a Kentucky citizen, who ingested Digitek® pursuant to a physician's prescription and suffered serious personal injuries as a result of her ingestion of Digitek®.

7. Lorena Ard was at all times relevant herein an Indiana citizen, who ingested Digitek® pursuant to a physician's prescription and suffered serious personal injuries, and was treated for those personal injuries, in Kentucky as a result of her ingestion of Digitek®.

8. Mary Bond was at all times relevant herein a Kentucky citizen, who ingested Digitek® pursuant to a physician's prescription and suffered serious personal injuries as a result of her ingestion of Digitek®.

9. Regene Fleming was at all times relevant herein a Kentucky citizen, who ingested Digitek® pursuant to a physician's prescription and suffered serious personal injuries as a result of her ingestion of Digitek®.

10. Defendant, Actavis Totowa, LLC ("Actavis") is a corporation organized and existing under the laws of Delaware with its principal place of business in New Jersey at 101 East Main Street, Little Falls, New Jersey 07424-5608.

11. At all material times hereto, Actavis :

a. is, and was, engaged in the business of the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Digitek® in the United States and Kentucky either directly or indirectly through third-parties or related entities;

b. is, and was, in the business of profiting from the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Digitek®;

c. conducted continuous and substantial business in the Commonwealth of Kentucky;

d. acted and gained knowledge itself and by and through its various agents, servants, employees, and or ostensible agents.

12. Defendant, Mylan Pharmaceuticals, Inc. ("Mylan") is a corporation organized and

existing under the laws of West Virginia with its principal place of business in New Jersey at 1405/1425, Route 206, South Bedminster, New Jersey 07921.

13. Defendant UDL Laboratories, Inc. ("UDL") is a corporation organized and existing under the laws of West Virginia with its principal place of business in Illinois at 1718 Northrock Court, Rockford, Illinois.

14. At all materials times hereto, Mylan:

a. is and was, engaged in the business of the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Digitek® in the United States and Kentucky either directly or indirectly through third-parties or related entities;

b. is, and was, in the business of profiting from the design, development, manufacture, production, processing, compounding, formulating, testing, sale, marketing, labeling, packaging, dosing, advertising, promotion, supply, releasing and/or distribution of Digitek®;

c. conducted continuous and substantial business in the Commonwealth of Kentucky;

d. acted and gained knowledge itself and by and through its various agents, servants, employees, and or ostensible agents.

I. FACTUAL ALLEGATIONS

A. The Drug - Digitek® (digoxin tablets, USP)

15. Digitek® is the brand-name of one of the cardiac glycosides, a closely related group of drugs having in common specific effects on the myocardium of the heart.

16. Digitek® is widely prescribed and used by millions of Americans to treat various heart conditions, including atrial fibrillation, atrial flutter and congestive heart failure.

17. Digitek® and digoxin are metabolized in the liver but excreted by the kidney.

18. Digitek® is approved only for sale and distribution in the United States in the following dosages (collectively referred to hereinafter as the "approved dose"):

a. Digitek® (digoxin tablets, USP) 0.125 mg; and

b. Digitek® (digoxin tablets, USP) 0.250 mg.

19. Each Digitek® tablet is approved by the United States Food and Drug Administration ("FDA") only for sale and distribution if it contains the labeled amount of digoxin.

20. Digitek® tablets manufactured and produced with an amount of digoxin in excess of the labeled dose are not approved for sale or distribution in the United States (hereinafter "unapproved excessive dose").

B. The FDA Warning Letters

1. The August 15, 2006 FDA Warning Letter

21. Upon information and belief, some of the recalled Digitek® was designed, developed, manufactured, produced, processed, compounded, formulated, tested, sold, marketed, labeled, packaged, dosed, advertised, promoted, supplied, released, and/or distributed from a plant in Little Falls, New Jersey owned by Actavis, which was acquired in December 2005 as part of Actavis' acquisition of another company's generic business.

22. On or about August 15, 2006, the FDA issued a warning letter to Actavis for failing to file periodic safety reports at its solid oral dose manufacturing facility in Little Falls, New Jersey (hereinafter referred to as the "August, 2006 Warning Letter").

23. The August, 2006 Warning Letter is available on the FDA's website at http://www.fda.gov/foi/warning_letters/archive/g6235d.htm. In the August, 2006 Warning Letter, the FDA warned Actavis that it had violated its adverse medical event reporting

obligations by marketing drugs without proper clearance and causing at least 26 adverse drug experiences (ADEs) by not submitting periodic safety reports.

24. According to the FDA's August, 2006 Warning Letter, an FDA inspection between January and February 2006 revealed that there were six potentially serious and unexpected adverse drug events dating back to 1999 for products, including digoxin, that were not reported to the agency.

25. The FDA's August, 2006 Warning Letter also warned Actavis about not properly investigating serious and unexpected ADEs, not adequately reviewing ADE information and failing to file periodic safety reports which resulted in at least 26 ADEs which were never reported. The FDA's August, 2006 Warning Letter also warned Actavis that it had not developed procedures for the surveillance, receipt, evaluation and report of adverse events.

2. The Revised Warning Letter About Actavis' "Significant Deviations" from the Current Good Manufacturing Practice Regulations.

26. On or about February 1, 2007, the FDA issued a revised Warning Letter to Actavis (hereinafter the "Revised Warning Letter") citing "significant deviations from the current Good Manufacturing Practice regulations."

27. In the Revised Warning Letter, the FDA noted several deviations from good manufacturing process, resulting in the adulteration of drug products manufactured by Actavis, that were observed by the FDA during an inspection conducted July 10, 2006 to August 10, 2006.

28. According to the FDA's Revised Warning Letter:

Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and release into the interstate

commerce by your firm have the identity, strength, quality and purity that they purport to possess.

29. The deviation from good manufacturing process observed by the FDA were presented to Actavis on an FDA-483 (list of Inspections) at the close of the inspection on August 10, 2006.

30. The FDA's Revised Warning Letter cited deficiencies in the operations of Actavis' quality control unit, which included instances where the unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results for drug products. Specifically, according to the Revised Warning Letter:

> Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products and ultimately were released for distribution into interstate commerce. Additionally, out investigators uncovered out-of-specification test results in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

31. The FDA's Revised Warning Letter stated that the FDA found during its inspection that analysts did not always document the preparation and testing of samples at the time they were done:

> Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly. [21 CFR 211.186(b)(9) and 21 CFR 211.188(b)(10)]

32. The FDA also cited a failure to check for accuracy the input and outputs from a system used to run the high-performance liquid chromatography during analysis of drug products.

33. Among other deficiencies cited by the FDA in the Revised Warning Letter were:

a. failure of the quality control unit to recognize that some tablets did not meet in-process specifications;

b. a lack of adequate procedures for conducting bulk product holding time studies;

c. failure to identify and control rejected in-process materials;

d. not adequately qualifying select equipment; and

e. failure to establish and follow written procedures for maintaining manufacturing equipment.

34. By way of example, the FDA Revised Warning Letter states that:

> Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment was adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example:
>
> a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: Amidal Nasal Decongestant; Amigesic Caplets, 750mg; Carisoprodol and Aspirin Tablets, USP, 200mg/325mg; Carisoprodol Tablets, USP, 350mg, Chlorzoxazone Tablets, USP, 250mg and 500mg; **Digoxin Tablets, USP, 0.25mg.**

35. The FDA gave Actavis, 15 working days to provide a written listing of all released lots of finished drug products that remain within specification that are associated with any out-of-specification test results during manufacture and to provide a description of the actions taken to ensure that lots were suitable for release.

C. The Manufacture, Production, Labeling, Distribution and Sale of Dangerous Digitek® Tablets Containing an Amount of Digoxin Exceeding the Labeled Dose Including Some With a Dose Exceeding that Approved for Medical Treatment in Humans

36. The Defendants are drug companies that, upon information and belief, engaged in the design, development, manufacture, production, processing, compounding, formulating,

testing, sale, marketing, labeling, packaging, dosing advertising, promotion, supply, releasing and/or distribution of Digitek® tablets containing an amount of digoxin, exceeding the dose on the label.

37. At all times relevant to this action, Defendants knew and/or had reason to know that the Digitek® was not safe for the patients for whom the drug was prescribed because the excess dose of digoxin can cause serious medical problems, digoxin overdose, digitalis toxicity and, in certain patients, catastrophic injuries and death.

D. The Class I Recall in the United States and Defendants' Failure to Provide Full, Complete and Adequate Information About the Recalled Digitek®

38. On or about April 25, 2008, the United States Food and Drug Administration ("FDA") announced a Class I Recall of all lots of Bertek and UDL Laboratories Digitek® (referred to previously and hereinafter as the "Recalled Digitek®"). The FDA announcement is available at http://www.fda.gov/medwatch/safety/2008/safety08.htm#Digitek. In sum, it stated that Actavis had notified health care professionals of a Class I nationwide recall of all strengths of Digitek®, a drug used to treat heart failure and abnormal heart rhythms, distributed by Mylan and UDL because of the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient.

39. Class I Recalls are instituted only when there exists a reasonable probability that use of the product will cause serious injury or death.

40. The Digitek® is an adulterated drug and its label and packaging are misbranded.

41. As of the date of this Complaint, Defendants have released little additional information about the Digitek® beyond a Press Release discussed in paragraph 45.

42. Defendants have failed to inform the medical community and the public, including the Plaintiff and/or Plaintiffs' families:

a. How many, and which lots of Digitek® contained amounts of unapproved digoxin;

b. How long Defendants manufactured and produced the Recalled Digitek® and how long the adulterated drug was supplied, sold, distributed and released into the stream of commerce;

c. How many "reports of illness and injuries have been received"; and

d. The nature and extent of reports of illness and injuries that were received.

43. Defendants' failure to provide the medical community, the public, Plaintiff and Plaintiffs' families with full, complete and adequate information about the Digitek®, including the information set forth in the preceding paragraph, is consistent with the safety violations which led the FDA to issue the August, 2006 Warning Letter referenced above.

E. The Well-Known Serious and Life-Threatening Injuries from Digoxin Overdose and Digitalis Toxicity

44. Digoxin overdose and digitalis toxicity can cause serious and life threatening personal injury and death.

45. Non-approved, excessive doses of digoxin significantly increase the likelihood that overdosed patients will experience the known side effects and reactions that can result from the approved doses of digoxin. In other words, the risk and dangers of approved doses are enhanced by an overdose of digoxin.

46. Doses of digoxin exceeding the dose prescribed by a physician for medical treatment can cause personal injury and/or death.

47. The Digitek® was adulterated, misbranded, defective, unreasonably dangerous and unfit for its intended uses. Defendants placed tens of thousands of patients, including Plaintiffs, unnecessarily at risk of serious injury and/or death and caused Plaintiffs to suffer

personal injuries and/or death, including medical expenses and/or anxiety and fear induced from ingesting the defective and misbranded drug, and the cost of the defective pills themselves.

48. Defendants knew or should have known about the manufacturing and production defects, misbranding, and negligent sale and distribution of the Digitek® and had a duty to design, develop, manufacture, produce, process, compound, formulate, test, sell, market, label, package, dose, advertise, promote, supply, release and/or distribute only safe Digitek® with approved doses of digoxin and doses of digoxin that were consistent with the dose on the label.

49. Defendants knew or should have known that they designed, developed, manufactured, produced, processed, compounded, formulated, tested, sold, marketed, labeled, packaged, dosed, advertised, promoted, supplied, released and/or distributed Digitek® with excessive unapproved amounts of digoxin before:

a. any of the Digitek® was released for distribution and sale; and

b. they mislabeled the Digitek®.

50. Defendants failed to implement or utilize adequate safeguards, tests, inspections, and quality assurance procedures to ensure the accuracy of the strength of Digitek®.

51. Defendants failed to implement or utilize adequate testing, including batch testing, batch dose verification, and other procedures, safeguards, and inspections to confirm, monitor and assess the quality, dose and safety of Digitek®.

52. Plaintiffs were prescribed Digitek® but unwittingly ingested Digitek®.

53. As a direct and proximate result of the Defendants' conduct and the defective and unreasonably dangerous condition of the Digitek®, the Plaintiffs suffered severe physical injuries and/or death.

54. As a direct and proximate result of the Defendants' conduct and the defective and unreasonably dangerous condition of the Digitek®, Plaintiffs seek to rescind the sale and seek

reimbursement of the amounts of money they spent for the purchase of the defective, misbranded, and adulterated Digitek®, together with attorneys' fees as a consequence of the sale of a known defective product unsuitable for its intended use.

55. As a direct and proximate result of the Defendants' acts and omissions, the Plaintiffs have suffered damages for medical, hospital, surgical, funeral and burial expenses and other expenses related to the diagnosis and treatment of Plaintiffs.

56. Based upon the allegations set forth herein, the defendants knew of facts that created a high degree of risk of physical harm to the Plaintiffs and the Defendants deliberately and/or recklessly proceeded to act in conscious disregard or indifference to that risk, and therefore and award of punitive damages is warranted.

II. CLAIMS FOR RELIEF

COUNT I – DEFECTIVE DESIGN

57. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

58. At all times material to this action, the Defendants were responsible for the design, development, manufacturing, production, testing, inspection, packaging, promoting, marketing, distributing, supply, labeling, release and/or sale of the Digitek®.

59. The Digitek® is defective and unreasonably dangerous to consumers.

60. The Digitek® is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

61. At all times material to this action, the Digitek® was expected to reach, and did reach, consumers in the Commonwealth of Kentucky and throughout the United states, including the Plaintiffs, without substantial change in the condition in which it was sold.

62. At all times material to this action, the Digitek® was designed, developed, manufactured, produced, tested, packaged, promoted, marketed, distributed, labeled, released and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the Digitek® contained an unreasonably dangerous design defect and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks that exceeded the benefits of the subject product, including but not limited to the risks of serious bodily injuries and death in an unacceptably high number of its users;

b. When placed in the stream of commerce, the Digitek® was defective in design and formulation, making the use of the Digitek® more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other digoxin medications and similar drugs on the market, including Digitek® with approved doses of digoxin, with doses that were consistent with the dose on the label.

c. The Digitek® design defects existed before it left the control of the Defendants;

d. The Digitek® was insufficiently tested and inspected;

e. The Digitek® caused harmful side-effects that outweighed any potential utility; and

f. The Digitek® was not accompanied by adequate instructions and/or warnings and labeling to fully apprise consumers, including the Plaintiffs, of the full nature and extent of the risks and side effects associated with its use and that it contained an overdose of digoxin, thereby rendering Defendants liable, individually and collectively, to the Plaintiffs.

63. Additionally, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or

significantly reduced the risk of injury to Plaintiffs without impairing the reasonably anticipated or intended function of the product. These safer alternative designs, including Digitek® with the approved dose of digoxin, consistent with the dose on the label, were economically and technologically feasible, and would have prevented or significantly reduced the risk of injury to Plaintiffs without substantially impairing the product's utility.

64. As a direct and proximate cause of Defendants' acts or omissions, the Plaintiffs suffered serious personal injuries and/or death.

COUNT II –MANUFACTURING DEFECT

65. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

66. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, producing, testing, packaging, inspecting, promoting, marketing, distributing, supplying, labeling, releasing and/or selling the Digitek®.

67. At all times material to this action, the Digitek® was expected to reach, and did reach, consumers in the Commonwealth of Kentucky and throughout the United States, including the Plaintiffs without substantial change in the condition in which it was sold.

68. At all times material to this action, the Digitek® was designed, developed, manufactured, produced, tested, packaged, inspected, promoted, marketed, supplied, distributed, labeled, released, and/or sold by the Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the Digitek® contained manufacturing defects which rendered the product unreasonably dangerous;

b. The manufacturing defects of the Digitek® occurred while the product was in the possession and control of the Defendants;

c. The Digitek® was not made in accordance with the Defendants' specifications or performance standards and/or those specifications and standards approved by the FDA; and

d. The manufacturing defects of the Digitek® existed before it left the control of the Defendants.

69. As a direct and proximate cause of the Defendants' acts and omissions, the Plaintiffs suffered serious personal injuries and/or death.

COUNT III –FAILURE TO WARN

70. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

71. The Digitek® was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained labeling, packaging and warnings insufficient to alert consumers, including Plaintiffs, of the dangerous risks and reactions associated with the Digitek®, including but not limited to, failing to warn that the Digitek® contained a dose of digoxin inconsistent with the dose on the label and sometimes a dose exceeding the approved dose for use by humans.

72. Plaintiffs were prescribed and used the subject product for its intended purpose.

73. Plaintiffs could not have discovered any defect in the subject product through the exercise of reasonable care.

74. The Defendants, as designer, developer, manufacturers, producers, suppliers, inspectors, testers, distributors, releasers or sellers of the subject Digitek®, a prescription drug, are held to the level of knowledge of an expert in the field.

75. The label, warnings and dosing information that were given by the Defendants failed to properly warn physicians, the Plaintiffs and the public that the Digitek® contained amounts of digoxin that were inconsistent with the amount on the label and sometimes contained a dose not approved for use in humans and thus ingestion risked serious injuries, side effects and/or death.

76. Plaintiffs, individually and through their prescribing physician(s), reasonably relied upon the skill, superior knowledge and judgment of the Defendants,

77. The Defendants had a continuing duty to warn the Plaintiffs of the dangers associated with the Digitek®.

78. Had the Plaintiffs received adequate warnings or information regarding the dose of digoxin in the Digitek® and/or information regarding the risks of ingesting the subject product, the Plaintiffs would not have used it.

79. As a direct and proximate result of the Defendants' conduct, Plaintiffs suffered serious personal injuries and/or death.

COUNT IV –BREACH OF EXPRESS WARRANTY

80. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

81. At all relevant times material to this action, Defendants warranted that the Digitek® was safe and not defective and/or unreasonably dangerous as stated above and warranted that it contained a dose of digoxin that was consistent with the dose set forth on its label and was otherwise safe for human ingestion.

82. At all relevant times material to this action, Defendants placed the Digitek® into the stream of commerce for sale and recommended its use to physicians, the FDA and consumers without adequately warning physicians, the FDA and consumers, including Plaintiffs, of the risks

associated with the use of the Digitek® and that it contained an amount of digoxin exceeding the labeled dose and sometimes exceeding the approved dose for human ingestion.

83. At all relevant times material to this action, Defendants had a duty to exercise reasonable care in the design, development, testing, manufacture, production, formulation, processing, compounding, labeling, packaging, inspections, supply, distribution, marketing, promotion, sale and release of the Digitek®, including a duty to:

a. Ensure that the product did not cause the user unreasonably dangerous side effects;

b. Ensure that the product was labeled accurately;

c. Ensure that the amount, strength and dose of the digoxin in the product was consistent with the dose set forth on the label and to ensure that the dose was approved by the FDA as a dose safe for use in humans;

d. Warn of dangerous and potentially fatal side-effects; and

e. Disclose adverse material facts when making representations to physicians, the FDA and the public at large, including Plaintiffs.

84. When the Plaintiffs' physicians prescribed the Digitek® and the Plaintiffs decided to use the Digitek®, both Plaintiffs and their physicians reasonably relied upon the Defendants and their agents to disclose known defects, risks, dangers, and side-effects of the Digitek® and whether the Digitek® contained a dose of digoxin, consistent with its label, and not in excess of the dose approved for ingestion by humans.

85. Plaintiffs, Plaintiffs' physicians and the FDA had no knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the Digitek® when Plaintiffs' physicians prescribed and/or otherwise provided Digitek® and Plaintiffs purchased and used the Digitek® as designed, developed, tested, manufactured, produced, dosed, inspected,

labeled, packaged, distributed, supplied, marketed, promoted, sold and otherwise released into the stream of commerce by the Defendants.

86. Plaintiffs justifiably and detrimentally relied on the warranties and representations of Defendants in the purchase and use of the Digitek®.

87. At all relevant times material to this action, Defendants were under a duty to disclose the defective and unsafe nature of the Digitek® to physicians, the FDA, consumers and users, such as Plaintiffs. Defendants had sole access to material facts concerning the defects, and Defendants knew that physicians, the FDA and users, such as Plaintiffs, could not have reasonably discovered such defects.

88. Defendants, its agents and employees expressly warranted to Plaintiffs and their physicians that the Digitek® was packaged and labeled accurately, that it contained the approved dose of digoxin, and that the drug was safe, merchantable and fit for its intended purpose.

89. Defendants breached this warranty because the Digitek® was misbranded, adulterated and did not contain the amount of digoxin as stated in the label and sometimes in excess of the approved dose for ingestion by humans, nor was it safe and effective as Defendants represented.

90. As a direct and proximate result of the Defendants' acts or omissions, Plaintiffs suffered serious injuries and/or death.

COUNT V –BREACH OF IMPLIED WARRANTY

91. Plaintiffs incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

92. The Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Digitek® for the treatment of certain cardiac problems.

93. At the time that the Defendants designed, developed, manufactured, marketed, produced, tested, inspected, distributed, supplied, released and sold the Digitek®, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

94. Plaintiffs, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

95. The Plaintiffs were prescribed, purchased and used the Digitek® for its intended purpose.

96. Because of the Defendants' wrongful conduct as described herein, Plaintiffs could not have known about the mislabeling, misbranding, excessive dose of digoxin, the nature of the risks and side-effects associated with the Digitek®. The recall of Digitek® occurred after Plaintiff's were injured and/or died.

97. Contrary to the implied warranty of merchantability, the Digitek® was not safe or fit for its intended uses and purposes and would not have been purchased had Plaintiffs been aware of the defects.

98. As a direct and proximate result of the Defendants' acts and omissions and the defective and unreasonably dangerous Digitek® and their breach of the implied warranty of merchantability, Plaintiffs suffered serious physical injuries and/or death.

COUNT VI --KENTUCKY CONSUMER PROTECTION ACT

99. Plaintiffs incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

100. Defendants are liable to the Plaintiffs pursuant to the Kentucky Consumer Protection Act (hereinafter "KCPA"). Defendants were in the business of manufacturing and marketing prescription drugs. Defendants and/or their agents designed, formulated,

manufactured, assembled, prepared for sale, distributed, and/or sold the prescription tablets which were in a defective condition unreasonably dangerous when applied to its intended use in the usual and customary manner.

101. Upon information and belief, privity existed between Plaintiff and Defendants.

102. Plaintiffs, while consuming said tablets in the usual and customary manner as they were intended to be used, suffered substantial injuries and/or death as a proximate result of Defendants placing the product on the market, which was unreasonably dangerous and defective at the time it was placed on the market by Defendants.

103. The tablets, at the time of the Plaintiffs' injuries and damages, were in substantially the same condition as they were at the time they were marketed by the Defendants.

104. As a direct and proximate result of Defendants' defective and unreasonably dangerous product, the Plaintiffs suffered serious injuries and/or death, plus a loss of monies paid for all defective and/or recalled tablets.

COUNT VII --CONSTRUCTIVE TRUST/UNJUST ENRICHMENT

105. Plaintiffs incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

106. Defendants' actions and inactions have caused them to be unjustly enriched at the hands of the Plaintiffs and all others similarly situated.

107. Defendants have acquired numerous benefits as a result of their fraudulent actions and/or, even if not fraudulent, it would be inequitable to permit Defendants to retain these benefits and/or the Plaintiffs are beneficially entitled to the benefits against Defendants who, against the rules of equity and against good conscience, either have obtained or hold and enjoy legal title to property that in justice they should not hold and enjoy. Said benefits include, but are not limited to, proceeds and profits derived from the sales of the defective products.

applicable exemplary and punitive damages;

6. All pre-judgment and post-judgment interest; and

7. Any other relief that this Court deems to be just and equitable.

Respectfully submitted,

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